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CropLife Europe letter on the Transparency Regulation implementation status

Dear Dr Berend,

CropLife Europe would like first to reiterate its commitment towards the objectives of the Transparency Regulation and we welcome the extensive work which has been done at Commission and EFSA level to try to get elements ready for the application date of 27th March 2021. Despite all these efforts, we still have many unanswered questions, and in many cases, the responses provided are of limited value to actual applicants.

IUCLID data format

We would like to highlight that CropLife Europe members are supportive of using IUCLID as the new data format for active substances applications and welcomes online submissions. However, not all software components are completely released or accessible (report generator, validation rules, dissemination rules), and the announced technical manuals and guidance for pesticides dossiers in IUCLID have not been published. This hinders the efficient and reliable preparation and management of pesticide dossiers. This applies especially in the context of submissions by task force which applicants are requested to form whenever possible.

We understand EFSA aimed at having a Minimal Viable Product for the 27th March but it has not been defined how applicants should deal with this and there is a lack of understanding in the applicant community on how EFSA and Member States are expecting data fields to be filled for the major extent of use cases. **Today, the introduction of innovation, with new Active Substances applications, is *de facto* hindered by the lack of certainty for applicants which is not acceptable.** Decisions are being taken to delay applications with consequences on companies planning and down the line, delays in farmers receiving new solutions. **We understand filtering of confidential information will not be possible for submissions after the 27th of March and companies will not be able to protect personal data as required by the GDPR.**

We support the use of structured information if it helps the scientific evaluation work and does not create duplication of efforts. That is why until we get full clarity on what is feasible and required, CropLife Europe will recommend its member companies to:

- Within IUCLID, make extensive use of document attachment functions including sanitized versions where applicable. Some of these approaches have already been agreed upon within the Hypercare programme for certain document types (*ie* residue field trials)
- Within IUCLID, complete structured data fields only for:
 - administrative part of the OECD Harmonized Templates (OHTs).
 - justifications for confidentiality claims
 - substance and mixture characterization
 - literature references

Such an approach will meet the current validation criteria of IUCLID and will facilitate Member States work by having access to documents (pdfs), including those summary documents Member States are asking for. Whilst a report generator is welcome, until this is demonstrably shown to provide full documentation necessary to assist Member States in providing DARs/RARs, **we believe our approach is a suitable interim solution to prevent delays in the approval/renewal process.** It will also respect the core objective of the regulation and allow the general public an easy access to all information contained in dossiers.

Moving forward, **CropLife Europe suggests suitable milestones should be defined with regards to stability for both IUCLID features and endpoint / study summary records.** Our companies will continue providing input and feedback for further development of IUCLID. For each IUCLID release, the best mixture of established and matured structured information and traditional unstructured information should be determined and documented in guidelines, with suitable transition periods.

Notification of studies database

The obligation for many business operators to notify newly commissioned studies will start in less than a month and we still are not able to test the system ourselves, even with dummy entries. This is becoming critical as internal processes in many companies will need adaptations as this requirement will affect the day to day operations. **We would request an urgent access to the database, even a partial or demo version, on which applicants and laboratories could gain experience.** We want to be compliant with the regulation as from the 27th March and so will need to make notifications within hours. Once business operators key contact will be approved, additional contacts will need to be added. **To do that we need answers to key questions prior to the EFSA webinar scheduled for the 16th March.**

Dissemination portal

We understand EFSA is still working on its dissemination portal. It is unfortunate to see that only a video has been announced for the 27th March. It would be important for applicants to understand how their documents and information will be actually shared with the general public, not only for renewals of active substances but also for imminent MRL or new active substances submissions after the 27th of March.

We would welcome any opportunity to discuss these issues directly. Should you have any questions please do not hesitate to contact me.

Yours sincerely



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